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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,487	01/07/2002	Spiros Fotinos	366325-509	3570

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,487	FOTINOS ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and request for extension of time, al filed 03/26/04. Claims 1-8 and 10-23 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 5 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to said claims.

Claim Rejections - 35 USC § 102

2. Claims 1-4, 6-8, 20 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lorenz et al. (US 5,420,197).

Applicants argue that Lorenz discloses a wet gel, which is pre-dissolved and which does not dissolve when applied to the skin and applicants mixture/composition is dry.

3. Applicants' arguments filed 03/26/04 have been fully considered but they are not persuasive.

A gel does not necessarily have to be wet. The instant recitation that the delivery device "dissolves on wetted skin tissue or mucosal epithelial tissue of a subject when applied thereto" refers to what happens to the delivery device. The prior art meets the limitation of a delivery device/disc/disk/patch that comprises a filmogenic polymer and active substance. The prior art reference of Lorenz meets the limitation of a transdermal disc/patch that contains an active substance and a filmogenic polymer, which in Lorenz is polyvinylpyrrolidone.

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4. Claims 1, 3 and 21 remain rejected under 35 U.S.C. 102(b) as being anticipated by Leonard et al. (US 4,820,525).

Applicants argue that the Leonard teaches a non-porous patch that contains polyethylene foamed material and having an occlusive backing and thus, the composition would not inherently dissolve when applied to mucosa.

5. Applicants' arguments filed 03/26/04 have been fully considered but they are not persuasive.

The instant claims do not exclude non-porous composition. The presence of occlusive backing does not prevent the layer containing the active agent from dissolving. Besides, dissolution of the disc is what happens to the disc upon application to a wet skin. What the instant generic claim requires is a filmogenic polymer and active substance, which delivery device/patch/disc/disk is disclosed by Leonard. If the instant delivery disc dissolves upon application to the skin, the delivery device that contains a filmogenic polymer and an active substance would also dissolve.

Claim Rejections - 35 USC § 103

6. Claims 10-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al. (US 5,420,197). Claim 23 is included in this rejection. Therefore, claims 10-19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lorenz et al. (US 5,420,197).

Applicants argue that Lorenz does not disclose dry composition that dissolves when applied to wetted skin and that the composition of Lorenz includes water.

7. Applicants' arguments filed 03/26/04 have been fully considered but they are not persuasive.

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The gel of Lorenz is not necessarily wet even when the starting materials include water. Since the composition of Lorenz contains a filmogenic polymer and an active substance and surfactant, the composition of Lorenz would also suffer the same fate when applied to a wetted surface. The presence of surfactant in the composition lends itself to foaming or lathering when wetted and it would be obvious to rinse it off.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 3, 6, 8 and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 42, 43, 45-47 of copending Application No. 09/340,338. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between instant claim 1 and co-pending claim 42 is the copending claim 42 recites the intended use of the device. Co-pending claims 43, 45, 46 relate to the filmogenic polymer, which is also described by instant claims 8 and 15. Instant claim 3 and 6 define what the active substances are, in the same token, co-pending claim 47 defines the therapeutic agents. Since the instant delivery device can be applied

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to the skin, it would have been obvious to one of ordinary skill in the art to apply the instant disc to the skin and expect the device to provide the desired effect on the area of application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Blessing Fubara
Patent Examiner
Tech. Center 1600